

## **REMARKS**

Claims 1-13 are pending in the application, with the independent claims, namely, claims 1, 6 and 10 being amended hereby.<sup>1</sup> In the Official Action mailed February 9, 2006, Examiner rejects most of the claims (including all of the independent claims) based on Bialecki and Luther,<sup>2</sup> with some of the dependent claims being rejected on the further basis of Bell. Applicant will focus the remarks herein on the independent claims as it is believed that they distinguish over the applied art thus rendering moot any further rejections as regards the dependent claims. As a consequence, however, for present purposes, and without waiver of the right to present further arguments as to any art and/or claims, it is submitted that resolution of the combination of Bialecki and Luther places the case in condition for allowance.

Examiner recognizes that the invention is directed to a protected needle catheter insertion device including a bent area in the needle. However, there is more to that bent area than merely bending, as there are certain relationships of the needle parts that are to be achieved with the bend. In that regard, Examiner will see in the figures of the present application that the needle actually has two generally parallel sections, one including the sharp tip at the distal end of the needle, and the other being the portion of the needle extending from the needle hub at the proximal end thereof. As a result of the

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<sup>1</sup> Applicant notes that a Preliminary Amendment was submitted on December 14, 2005. The Official Action, however, references only the application without mention of that Preliminary Amendment. The Preliminary Amendment corrected minor wording and claim dependency errors and those corrections are reflected herein. Applicant points this situation out so that Examiner will understand that the changes to the claims shown hereinabove are as against that Preliminary Amendment, and not as against the claims as originally filed.

<sup>2</sup> Applicant notes that Luther, cited by Examiner as 2002/0103463, issued as U.S. Patent No. 6,585,704 cited by Applicant in the Information Disclosure Statement e-filed on January 17, 2005, and checked off as considered by Examiner.

bent area, the two portions of the needle to either side of the bend define longitudinal axes that are offset from each other and are also generally parallel to one another. Also, bevel 42 forming part of the sharp tip is maintained at an angle to the longitudinal axis of the needle so that it continues to present the same "needle" appearance and function as if there had been no bend. Consequently, the needle of the present application is not merely a shaft with a curved tip end.

By contrast, the art cited by Examiner fails to teach a needle with a bent area as claimed by Applicant. For example, Examiner points to Bialecki for a teaching of protected needle catheter insertion devices, but acknowledges that Bialecki does not teach a bent needle. Indeed, Bialecki is merely one example of protected needle catheter insertion devices, which for purposes of the invention as previously and currently claimed, are also characterized by other art already of record. A bent needle is not a feature thereof. Instead, Examiner looks to Luther for a teaching of a bent needle. The bent needle of Luther is not the presently claimed bent needle, however, such that even if Luther were combined with protected needle catheter insertion devices exemplified by the art of record (including Bialecki), the result would not be the claimed invention.

In particular, the very essence of the Luther reference is a Huber or other similar needle. In that type of needle, the bend is actually a curve extending through the tip such that the "edge 38 of the opening 34 at the tip of the needle [is] parallel to the axis of the needle 32." Luther, para. [0024]. Luther goes on to explain that such a relationship is important for that type of needle. The foregoing is dramatically different from the needle with the bent area as claimed here.

Taking first independent claim 1, the claim has been amended to recite that the distal end "includ[es] a sharp tip with a bevel" and that "no portion of said bevel is in said bent area". Further, claim 1 has been amended to make clear that the "bevel extend[s] at an angle relative to said longitudinal axis". Luther, however, deals with needles with "bent tips" (Luther, para [0025]). In other words, the bend in Luther actually extends through to the tip such that the edge 38 (which is not necessarily even a bevel) is in the bent area and is parallel to the longitudinal axis, as opposed to at an angle. Luther's bent needle thus does not meet the limitations of claim 1 such that combining Luther with Bialecki (or any of the other similar art of record) does not result in the claimed invention. Hence, claim 1 is submitted to be patentable and allowance thereof is respectfully requested.

The same result obtains as regards independent claims 6 and 10. In those claims, they have always recited that the distal and proximal ends have "off set" longitudinal axes. Where are these axes in Luther? Due to the curved end tip in Luther, it appears more likely that if there are even two such axes, they actually intersect rather than off set. In any event, to make the distinction more clear, claims 6 and 10 have been amended to recite that the longitudinal axes are generally parallel. That is clearly not the case for Luther's bent needle. Thus, Luther alone, or in combination with the protected needle catheter insertion art of record, fails to teach or suggest the bent needle as claimed by Applicant. Accordingly, claims 6 and 10 are likewise submitted to be patentable and allowance thereof in order.

Because the independent claims are patentable, as explained above, the dependent claims are likewise patentable for at least those same, respective, reasons.

Applicant will thus not address the dependent claims at this time so as to streamline prosecution, but reserves the right to address such claims if necessary.

### **Conclusion**

In view of the foregoing, Applicant respectfully submits that all outstanding issues in the Official Action have been addressed, and that the pending claims are in condition for allowance. Applicant therefore solicits a formal Notice of Allowance at the earliest opportunity. If any issues remain, Examiner is respectfully asked to telephone undersigned attorney in an effort to promptly resolve same.

No fee is believed due for this filing. If any fee is due, consider this as an authorization to charge deposit account 23-3000 therefor.

Respectfully submitted,

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